ADVANCE TOPICAL ANESTHETIC GEL- benzocaine gel The Atlanta Dental Supply Company DBA Advanced Dental Products

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active Ingredients

Benzocaine 200mg (in each g)

Purpose

Oral Anesthetic

Use

For oral mucosal use only, as directed by dentist. For the temporary relief of pain due to minor dental procedures.

Warnings

Methemoglobinemia warning: Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in the blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops:

- pale, gray or blue colored skin (cyanosis)
- headache
- rapid heart rate
- shortness of breath
- dizziness or lightheadedness
- fatigue or lack of energy

Allergy Alert: Do not use on patients with a history of allergies to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics.

Do not use

- for more than 7 days unless directed by a physician. If sore mouth symptoms do not improve in 7 days; irritation, pain or redness persists or worsens; or if swelling, rash or fever develops, see your physician promptly.
- for teething
- in children under 2 years of age

When using this product Avoid contact with eyes. If contact occurs, flush with water.

Do not exceed recommended dos age. If more than used for pain is accidentally swallowed, get medical help or contact a Poison Control Center right away.

If pregnant or breast feeding, ask a physician before use.

Keep Out of Reach of Children.

Directions

- Apply only amount needed to the oral mucosa to prevent or relieve pain.
- children under 2 years of age: do not use

Other Information

Store at 59° -86°F (15 - 30°C). Protect from freezing.

Inactive ingredients

Iflavoring, PEG 3350, PEG 400, sodium saccharin, water. May contain blue #1, green #3, green #5, red #3, red #28, red #40, yellow #5, (tartrazine), yellow #6, as a color additive.

Questions or comments?

OPEN HERE

Drug Facts

Call: 877-896-7341

Manufactured for: Advanced Dental Products Atlanta, GA 30359

Advancing the Quality of **Dental Care Products**

GLUTEN FREE! Advance
SLUTEN FRE 20% Benzocain 1 fl. oz. (30 m
Anesthetic Gel 20% Benzocaine 1 fl. oz. (30 ml)

Made in USA

mouth symptoms do not improve

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Questions or comments? Call: 877-896-7341 Rev 06/2018

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If pregnant or breast feeding

ADVANCE TOPICAL ANESTHETIC GEL

benzocaine gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:71347-100

Route of Administration DENTAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength

BENZOCAINE (UNII: U3RS Y48 JW5) (BENZOCAINE - UNII: U3RS Y48 JW5)

BENZOCAINE
200 mg in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)		

WATER (UNII: 059QF0KO0R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
D&C RED NO. 28 (UNII: 767IP0 Y5NH)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics			
Color	pink	Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

ı	Packaging				
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
ı	1 NDC:71347-100-30	30 g in 1 JAR; Type 0: Not a Combination Product	06/01/2018		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	0 3/0 1/20 17	

 $\pmb{Labeler} \textbf{-} \textbf{The Atlanta Dental Supply Company DBA Advanced Dental Products (033505389)}$

Revised: 11/2018 The Atlanta Dental Supply Company DBA Advanced Dental Products